

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. Claim Status and Amendment**

Claims 16-41 were pending in this application when last examined and stand rejected. Claims 1-16 were previously cancelled without prejudice or disclaimer.

Claims 17, 24-26, 28-37, and 39 have been cancelled by way of the present amendment without prejudice or disclaimer. Claims 16, 18-23, 27, 38, and 40-41 have been amended by way of this response to address the formal matters raised in the Office Action and to better conform to US claim form and practice. Also, new dependent claim 42 has been added.

Claims 16, 18-23, 27, 38, 40-42 are pending in this application upon entry of this amendment.

Support for the subject matter of amended claim 16 can be found throughout the general disclosure, see for example, the abstract, the paragraph beginning at page 3, line 22, and the paragraph beginning at page 9, line 29 of the specification, and original claim 16.

Support for the amended subject matter in claim 18-23, and 27 can be found at least in the paragraph starting at page 3, line 22 and the paragraph starting at page 4, line 8 of the specification.

Support for the amended subject matter in claim 38 can be found at least in the paragraph starting at page 4, line 20 of the specification.

New claim 42 has been added to replace claim 28 (now cancelled). Support can be found at least by the paragraph starting on page 4, line 6 of the specification as well as the Figures of the present application and previous claim 28.

No new matter has been added in the current amendment.

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

## **II. Priority under 35 U.S.C. § 119**

Applicants note with appreciation the acknowledgement in item 1 on page 2 in the Office Action Summary of the foreign priority claim and receipt of Applicants' papers filed under § 119.

## **III. Objection to the Drawings**

The Examiner objected to the drawings under 37 CFR 1.83(a) as failing to show the following features of the claims: the fitting element, cervical collar, restriction member, lock member, holes, dents, chin lift collar, and movable mover for the reasons set forth in item 2 on page 2 of the Office Action. The objection is respectfully traversed.

Applicants have amended the claims, figures, and specification of the present application in a manner believed to address the issues raised by the Examiner. See also the discussion below with respect to the traversal to the objections to the specifications. Specifically:

The fitting element, holes, dents, and movable mover

As to the term “holes” and “dents” in claims 24-26, and the terms “fitting element” and “movable mover” in claim 28, these claims have been cancelled without prejudice or disclaimer. Thus, the objection of these terms is moot.

Cervical collar

Applicants have amended Figure 1 and the paragraph beginning at page 10, line 19 of the specification to include a reference number 50, referring to the cervical collar as shown in the original Figure 1.

Restriction member

Applicants have amended the paragraphs begin at page 5, line 26, page 6, line 25, page 10, line 21, page 15, line5, page 16, line24, and page 19, line 16 of the originally filed specification to clarify that reference number 260, referring to block 260, is the restriction member. Support of this amendment can be found at least at the paragraph starting on page 3, line 27 of the specification, which recites: “the aforementioned collar additionally comprising a restrictor member restricting the motion or location of the jaw clasp relative to the rigid frame; and/or wherein the restrictor limits the distance between the rigid frame and the jaw clasp and/or wherein the restrictor limits the direction of motion between the rigid frame and the jaw clasp.” Thus, the specification clearly supports the term “restriction member” and no new matter is added to this amendment.

Lock member

Applicants have amended the paragraphs starting at page 5, line 26, page 10, line 21, page 15, line5, and page 16, line24 of the originally filed specification to clarify that reference number 250, referring to block 250, is the lock member. Support for this amendment can be found at least at the paragraph that beings at page 4, line 4 of the

originally filed specification, which recites “the aforementioned collar additionally comprising a lock member preventing the motion of the jaw clasp relative to the rigid frame.” Thus, the specification clearly supports the term “lock member” and no new matter is added.

Chin lift collar

Applicants have amended the Figure 30 and the paragraph starting at page 21, line 17 of the originally filed specification to designate the reference number 1310 to the ‘chin lift’ collar.

In view of the above, it is believed that the present amendments overcome the noted objections to the drawings. Withdrawal thereof is respectfully requested.

**IV. Objections to the Specification**

In item 3 on page 3 of the Office Action, the specification was objected on the basis that the “chin lift collar” in claim 27 is allegedly not disclosed therein. This objection is respectfully traversed.

Applicants respectfully submit that the specification provides adequate written support for the "chin lift collar". See, for instance, the paragraph beginning at page 21, line 17 of the originally filed specification, which recites: “Fig. 30 details a cervical collar comprising a ‘Chin lift’ collar according to yet one embodiment of the present invention wherein holding point...”. This statement provides literal support for the noted language. Thus, it is clear that the specification discloses the noted term. The objection is therefore untenable and withdrawal thereof is requested.

The Examiner also objected to the specification on the grounds that the “movable mover element” in claim 28 is allegedly not disclosed therein. For the sole purpose

of expediting prosecution and not to acquiesce to the objection, Applicants have amended claim 28 has been cancelled and replaced by new claim 42, which does not contain the objected language. Thus, the objection is moot. Withdrawal of this objection is respectfully requested.

**V. Written Description Rejections under 35 U.S.C. § 112**

Claims 29-36 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not provide written description support for a jaw clasp member that comprises an airway protector for the reasons in item 5 on page 3 of the Office Action.

For the sole purpose of expediting prosecution and not to acquiesce to the rejection, Applicants have cancelled claims 29-36 and amended the remaining claims so that the jaw clasp is no longer claimed as an independent invention, but rather as part of the cervical collar of claims 16 and new claim 42. Thus, it is believed that the present amendment overcomes the rejection and withdrawal thereof is requested.

**VI. Enablement Rejections under 35 U.S.C. § 112**

On page 4, item 6 of the Office Action, claims 37 and 39-41 were rejected under 35 U.S.C. § 112, first paragraph, on the base that the airway protector as described in any of the Figures 1-32 is allegedly not enabling.

For the sole purpose of expediting prosecution and not to acquiesce to the rejection, Applicants have amended the claims in a manner believed to obviate the rejection. Specifically, claims 37 and 39 have been cancelled and method claims 40-41 have been amended to be dependent from claim 38. It is believed that the specification fully enables the

method described in claims 38, and 40-41 for reasons which are self-evident. Thus, the enablement rejection of claims 37 and 39-41 has been overcome. Withdrawal of the rejection is requested.

#### **VII. Indefiniteness Rejections under 35 U.S.C. § 112**

Claims 18-27, 29-37, and 39-41 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons set forth in item 8 on page 4 of the Office Action.

This rejection is overcome, as applied to the amended claims, for reasons which are self-evident. Applicants have amended the claims, especially independent claim 16 to provide respective antecedent support to the rejected terms in claims 18-28, 29-37 and 39-41. This rejection has therefore been overcome. Withdrawal is respectfully requested.

#### **VIII. Rejection under 35 U.S.C. § 102**

Claims 16 – 41 were rejected under 35 U.S.C. § 102(b), as being anticipated by Nagata (US 5,575,763) for the reasons set forth in item 9 on page 5 of the Office Action. Applicants respectfully traverse this rejection.

The rejection should fall, because Nagata fails to disclose or suggest each and every element of the claims as required to establish anticipation under 35 USC §102.

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2131.

Nagata discloses a cervical orthosis for supporting the cervical spine. The cervical orthosis has a structure which is different from the structure of the cervical collar of independent claim 1, as amended, as discussed below. The cervical orthosis of Nagata

includes a front chest support and a rear back support. It also includes a brace for supporting elements of the face of the patient. However, Nagata fails to disclose or suggest a cervical collar having a jaw clasp attachable to the patient and that is adapted to for restricting the motion of the head and neck, while simultaneously maneuvering said jaw clasps attached to the jaw, in a forward and slightly downward direction such that airway maintenance with cervical spin control is provided as recited in amended claim 16.

Further, as disclosed in Nagata, the primary object of the aforementioned cervical orthosis is to provide extended long-term support for patients with spinal injury, so as to provide spinal support while at the same time allowing the patient to eat, talk and perform other functions with ease and comfort. Nagata also states that “[s]ince the cervical orthosis of the present invention does not restrain the mandible, the patient is able to comfortably open the mouth necessary in daily life, such as talking or eating a meal while wearing such a cervical orthosis” (See Col. 2, lines 34-48). Nagata also expressly discloses that when “the check brace pad are brought into contact with the mandible, such contact is not for restricting the movement of the mandible, but for urging it to separate from throat molds.” (See Col. 5, lines 5-9)

Applicants respectfully submit that one of ordinary in the art would understand from these recitations that Nagata does not even intend to restrain the function of the mandible. Therefore, any intention to maneuver the jaw clasp, which is attached to the mandible, would be contrary to the teachings of Nagata.

Maneuvering the jaw clasps in a forward and slightly downward direction is critical to maintain the airway of a patient open in an emergency situation. Because the cervical orthosis of Nagata does not restrain the mandible, it is not suitable for emergency trauma settings, as is the device of the present claims. In emergency trauma situations, it is

not enough simply not to restrain the mandible. Added measures must be taken in order to assure that the airways remain open since there exists the danger of the patient losing consciousness and of the airways closing automatically. It is a prerequisite of invasive surgical cricothyroidotomy to carry out tracheal intubation, or less invasive jaw thrust maneuvers (in combination with a cervical collar) in order to assure that airways remain open.

It is also not enough to simply leave the mandible unrestrained, as in the case of Nagata. Nagata provides a solution for every-day life situations where the patient is fully-conscious, in order to allow for easier eating and speaking. However, it is not satisfactory in trauma situations where, even if the mandible is unrestrained, the airways could close due to the patient losing consciousness. This is because the unrestrained mandible will fall backward in the direction of the airway (the oro-pharings) and thus block and close the airway. Using the claimed cervical collar, however, the mandible is actively pushed forward in the opposite direction, thus opening the airway, i.e., a novel effect provided by the novel device of the present claims, which is neither provided nor taught in Nagata.

The airway-protecting cervical collar of then claims is designed for both supporting the cervical spine and for actively keeping the airways open. The jaw clasp of the device both allows and promotes forward movement of the jaw so as to maintain open airways, and, where needed, allows for an easy performance of jaw thrust maneuvers.

Accordingly, Applicants respectfully submits that Nagata fails to disclose each and every feature of the amended independent claim 16, and Nagata does not even intend to maneuver jaw clasps in a forward and slightly downward direction, as recited in claim 16. Therefore, claim 16 is patentable over Nagata, and claims 18-23, 27, and 38-42 are also

patentable by virtue of their dependency from claim 16, and features recited therein.

Withdrawal of this rejection is therefore respectfully requested.

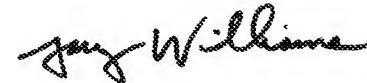
**IX. Conclusion**

In view of the above amendment and remarks, Applicants respectfully request withdrawal of the outstanding rejections of record. Applicants submit that the application is in condition for allowance and early notice to this effect is most earnestly solicited.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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Appendix

Replacement drawings for Figures 1 and 30 (both clean and annotated versions)